510(k) Summary
Tokuyama Dental Corporation
ESTELITE COLOR
K#110178

APR - 5 2011

The following information is provided pursuant to 21 CFR 807.92.

807.92(a)(1)

(i) 510(k) Submitter

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(ii) 510(k) Submitter Contact

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(iii) Preparation Date

March 15, 2011

807.92(a)(2)

Trade or Proprietary Name:	ESTELITE COLOR
Common Name:	tooth shade resin material
Classification Name:	material, tooth shade, resin
Product Code:	EBF

807.92(a)(3)

The ESTELITE COLOR device is substantially equivalent for purposes of FDA medical device regulations to multiple predicate devices. Specifically, for purposes of performance characteristics the device is substantially equivalent to Sybron Dental's KOLOR+ tooth shade resin material (K#961284), and for purposes of biocompatibility the device is substantially equivalent to Tokuyama's own E-1 ESTHETIC COMPOSITE SYSTEM tooth shade resin material (K#072746) and Tokuyama's own ESTELITE SIGMA QUICK tooth shade resin material (K#080940).

807.92(a)(4)

ESTELITE COLOR is a low viscosity light-cured tint for individualized shade characterizations. The device comes in a paste, packaged in a syringe. The device contains silica zirconia and silica-titania filler. All ingredients have been cleared for use by the FDA in similar devices.

Biocompatibility testing is not required because (i) all the ingredients in the ESTELITE COLOR device have already been authorized by the FDA for use in similar devices, (ii) the ESTELITE COLOR device is applied in small amounts below or in between layers of the composite restoration and is cured once applied, (iii) it is believed that no or almost no leaching of the ingredients occurs, and (iv) Tokuyama Dental Corporation has received no reports of any adverse incidents involving the ingredients used in the ESTELITE COLOR device except for extremely rare allergic reactions that affect one person approximately every two years.

The device does not come sterilized and is not intended to be sterilized prior to use.

807.92(a)(5)

The ESTELITE COLOR device is for masking discolorations and making individualized shade characterizations in direct and indirect resin restorations, applied below or in between layers of the composite restoration.

807.92(a)(6)

The ESTELITE COLOR device has the same basic technological characteristics in terms of design, material, and chemical composition as the predicate devices identified above. The ESTELITE COLOR device does not have an energy source.

Specifically, for purposes of design the device has the same basic characteristics as Sybron Dental's KOLOR+ tooth shade resin material (K#961284), as both devices are light-cured color modifiers to be used under or between layers of the composite restoration. For purposes of material and chemical composition, the ESTELITE COLOR device has the same basic characteristics as Tokuyama's own E-1 ESTHETIC COMPOSITE SYSTEM tooth shade resin material (K#072746) and Tokuyama's own ESTELITE SIGMA QUICK tooth shade resin material (K#080940), as the ingredients in the ESTELITE COLOR device are already authorized by the FDA for use in these two other devices.

807.92(b)(1)

Non-clinical testing of the physical properties of the ESTELITE COLOR device, including depth of cure and color stability after irradiation, were conducted in accordance with ISO4049:2009.

807.92(b)(2)

There were no clinical tests performed for the ESTELITE COLOR device.

807.92(b)(3)

Based on the non-clinical testing conducted of the physical properties of the ESTELITE COLOR device in comparison to the KOLOR+ tooth shade resin material predicate device (K#961284) as described above, it is concluded that the ESTELITE COLOR device is as safe, as effective, and performs as well as or better than KOLOR+ device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Tokuyama Dental Corporation
C/O Mr. Keith A. Barritt
Fish & Richardson P.C.
1425 K Street, N.W. 11th Floor
Washington, DC 20005

APR - 5 2011

Re: K110178
Trade/Device Name: ESTELITE COLOR
Regulation Number: 21 CFR 872.3690
Regulation Name: Tooth Shade Resin Material
Regulatory Class: II
Product Code: EBF
Dated: January 20, 2011
Received: January 21, 2011

Dear Mr. Barritt:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K110178

Device Name: ESTELITE COLOR

Indications For Use:

The ESTELITE COLOR tooth shade resin material is for masking discolorations and making individualized shade characterizations in direct and indirect resin restorations, applied below or in between layers of the composite restoration.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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